

Testimony of

The Honorable John L. Brownlee

July 31, 2007

STATEMENT OF JOHN L. BROWNLEE
UNITED STATES ATTORNEY
FOR THE WESTERN DISTRICT OF VIRGINIA
UNITED STATES DEPARTMENT OF JUSTICE
BEFORE THE COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE
CONCERNING

"ENSURING THAT DEATH AND SERIOUS INJURY ARE MORE THAN A BUSINESS COST: OXYCONTIN AND DEFECTIVE PRODUCTS"

PRESENTED ON JULY 31, 2007, AT 2:30 PM
ROOM 226 OF THE SENATE DIRKSEN OFFICE BUILDING

Chairman Leahy, Senator Specter, and members of the committee, thank you for convening this important hearing to discuss the prosecution and conviction of the manufacturer and distributor of the painkiller OxyContin and the company's top three executives. Professional career prosecutors from my office and the Department of Justice and dedicated State and Federal investigators spent over 5 years investigating Purdue and its executives. Convicting these defendants and bringing them to justice was a difficult and challenging endeavor, and I am grateful for the hard work and outstanding accomplishments of these members of law enforcement. They, in my judgment, represent the very best of the Department of Justice. Thank you for inviting me to be here, and I deeply appreciate the opportunity to appear before you today to offer my perspective on the investigation and convictions.

July 20, 2007 Plea Agreement

On July 20, 2007, in a Federal courthouse located in Abingdon, Virginia, the Honorable James P. Jones, Chief U.S. District Judge for the Western District of Virginia, accepted the guilty pleas of The Purdue Frederick Company, Inc., the manufacturer and distributor of OxyContin and its top three executives. Purdue pleaded guilty to a felony charge of illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers. Purdue agreed to pay \$600 million in criminal fines, forfeitures and civil recoveries. While the total settlement was based on the assessment of legally relevant factors and not on profits realized by Purdue, it should be noted that this figure reflects 90 percent of the company's profit on the sale of OxyContin during the time period of the offense. Purdue also was required to acknowledge that it illegally marketed and promoted OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse and diversion, and less likely to cause withdrawal symptoms than other pain medications when there was no medical research to support those claims. An affiliated company, Purdue Pharma, which will continue to market Oxycontin, will operate for five years under a corporate integrity agreement with the Department of Health and Human Services. This agreement requires extensive compliance measures and independent reviews. In addition, Purdue's former President and Chief Executive Officer Michael Friedman, General Counsel Howard Udell, and former Chief Medical Officer Paul Goldenheim pleaded guilty to a misdemeanor charge of misbranding OxyContin. These defendants were placed on supervised probation for 3 years, ordered to perform 400 hours of community service related to the prevention and treatment of prescription drug abuse, and collectively paid \$34.5 million in criminal fines.

Purdue Frederick Company

The defendant, The Purdue Frederick Company, a New York corporation headquartered in Connecticut, was created in 1892 and purchased by its current owners in 1952. Defendant Michael Friedman joined Purdue in 1985 and later

was appointed President and Chief Executive Officer. Mr. Friedman left Purdue two months ago. Defendant Howard Udell joined Purdue in 1977 and is presently Purdue's Executive Vice President and Chief Legal Officer. Defendant Dr. Paul Goldenheim joined Purdue in 1985 as its Medical Director. Dr. Goldenheim left Purdue in 2004.

OxyContin - Food and Drug Administration Approval and Marketing Practices by Purdue Frederick

In 1996, the Food and Drug Administration (FDA) approved Oxycontin controlled-release tablets for the treatment of moderate to severe, ongoing pain. Oxycontin contains oxycodone HCL, a narcotic with an addiction potential similar to that of morphine. Accordingly, OxyContin is a controlled substance and subject to regulation by the Drug Enforcement Agency. Oxycontin remains an approved prescription drug.

Backed by an aggressive marketing campaign, Purdue's OxyContin became a promising pain medication for many doctors and patients. Purdue claimed it had created a new, low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse than other pain medications.

But OxyContin was not what Purdue claimed it was. Purdue's assertions that OxyContin was less addictive and less subject to abuse and diversion were false - and the company knew its claims were false. Purdue's misrepresentations contributed to a serious national problem in terms of abuse of this prescription drug. Purdue's OxyContin did not offer a low risk way of reducing pain, as promised. Due, in part, to Purdue's aggressive and misleading marketing campaign, prescriptions for OxyContin increased from approximately 300,000 in 1996 to nearly 6 million in 2001. As OxyContin became more available, its abuse and diversion increased, and that increased availability had, in my judgment, a devastating effect on many communities throughout Virginia and the United States, as documented by the DEA and local law enforcement.

Early Legal Action

In response to the effects of OxyContin abuse and diversion, government officials and private citizens began focusing on Purdue and OxyContin. Product liability litigation began in Ohio in April, 2001. In 2000, the former U.S. Attorney for the District of Maine announced his awareness of the growing problem of OxyContin abuse in his state. In February 2000, he sent a letter to all of Maine's practicing physicians warning them about increasing problems with the illegal diversion and abuse of OxyContin. Also, the former U.S. Attorney for the Eastern District of Kentucky, in February 2001, launched Operation OxyFest arresting more than 200 OxyContin users and dealers. That U.S. Attorney, according to news accounts, called OxyContin abuse "an epidemic like some sort of locust plague rolling through southeastern Kentucky." There were also numerous reports from around the nation that OxyContin was being abused and diverted. In July 2001, FDA approved a new warning on Oxycontin's labeling concerning the drug's potential for abuse and issued a letter to healthcare professionals urging them to be alert to the potential for Oxycontin misuse, abuse, and diversion.

Chronology of Western District of Virginia's Investigation and Prosecution of Purdue

In the fall of 2001, just weeks after I was appointed U.S. Attorney in Virginia, we began our preparations for an investigation of Purdue, in conjunction with FDA's Office of Criminal Investigations. The Office of Inspector General of the Department of Health and Human Services and other investigative agencies later joined the investigation. The Western District of Virginia has 19 criminal prosecutors and 4 civil attorneys located in 4 staffed offices to cover the entire district of 52 counties and an approximate population of 2.2 million. Our Abingdon office, where this case was investigated and prosecuted, has three Assistant U.S. Attorneys and two support staff. In order to prepare for the investigation, we had to shift cases to our other attorneys, including myself, and recruit State prosecutors to help with our other criminal investigations.

On December 3, 2002, prosecutors from my office served an administrative health care subpoena on Purdue demanding corporate records related to the manufacturing, marketing and distribution of OxyContin. That subpoena, and the nearly 600 that followed over the next several years, represented the beginning of a difficult struggle between Purdue's counsel and the government for the necessary information we needed to conduct our review. Purdue's counsel fought hard and did the very best to protect the requested information and records. Once we began to receive the corporate records, every document was scanned into a computer database and reviewed. In addition to

reviewing several million records, we also conducted nearly 300 interviews of individuals who had some connection to Purdue or OxyContin marketing and distribution. To say the least, this was a time consuming and challenging process.

In the beginning of 2006, prosecutors began preparing a detailed prosecution memorandum and charging document. This was an effort to determine whether there was sufficient evidence to charge the company or any individuals. Although much of the evidence is protected under Federal Rule of Criminal Procedure 6(e), and I am therefore prohibited from divulging it, I think it is important to discuss for a moment that portion of the factual record that is not protected by 6(e), in order to give you a better understanding of the nature of the evidence in this case.

The Agreed Statement of Facts

According to the Government's evidence submitted to the Court in an Agreed Statement of Facts, Purdue's actions began in early 1995, when Purdue used focus groups of primary care physicians and surgeons to determine whether such physicians would be willing to prescribe OxyContin for patients with non-cancer pain. According to Purdue's research, many of these physicians had great reservations about prescribing OxyContin because of the drug's addictive potential and side effect profile, and its abuse potential. It was clear from these focus groups that physicians were concerned about the safety and risks of OxyContin.

Purdue also learned from these focus groups that physicians wanted a long lasting pain reliever that was less addictive and less subject to abuse and diversion. Purdue understood that the company that marketed and sold that drug would dominate the pain management market. And that is exactly what Purdue tried to do.

Purdue's Unlawful Marketing and Promotion of OxyContin

Despite knowing that OxyContin contained high concentrations of oxycodone HCL, had an abuse potential similar to that of morphine, and was at least as addictive as other pain medications on the market, Purdue, beginning in January 1996, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. Purdue did so in the following ways:

First, Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68 percent of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

Second, Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer opportunities for addiction than immediate-release opioids.

Third, Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids, resulting in less euphoria and less potential for abuse than short-acting opioids.

Fourth, Purdue falsely told certain health care providers that patients taking 60 mg or less could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug at lower doses.

And fifth, Purdue sales representatives, while promoting and marketing OxyContin, falsely told health care providers that the statement in the OxyContin package insert that "[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug," meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers. Purdue later amended the statement to read, "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is

believed to reduce the abuse liability of a drug." Nevertheless, Purdue continued to market OxyContin in the same manner as described above.

Response to the July 20, 2007 Convictions

Since these convictions were announced, there has been criticism of my decision to prosecute these cases. For example, on May 15, 2007, in an editorial published in the Wall Street Journal, Dr. Sally Satel, a resident scholar at the American Enterprise Institute, wrote that "the real public-health damage here comes from the pitched campaign conducted by zealous prosecutors and public-interest advocates to demonize [OxyContin] itself." Dr. Satel claimed that this prosecution and convictions will only make it harder for pain patients to get treatment and that "this newest injection of malignant hype is the last thing they need." Also, in a paper presented to the American Bar Association, defense attorneys wrote that requiring executives to plead guilty to misdemeanor offenses was unfair and suggested that Congress should consider removing the provision from the statute that holds executives and owners strictly liable for the criminal acts of their companies. In addition, a former U.S. Attorney from the District of Maine wrote a letter to Chief Judge Jones and called our prosecution of the executives "a case of unusual, if not unprecedented, use of prosecutorial discretion." Despite these criticisms, I am confident that the facts and law compelled a decision to proceed against this company and its executives, contrary to the positions taken by some.

Legal Basis for July 20, 2007 Convictions

Some have raised important questions regarding why we did not demand incarceration of the three executives. I would like to take a few moments to explain the government's reasoning for that decision. Michael Friedman, Paul Goldenheim, and Howard Udell pled guilty to strict liability misdemeanor offenses based on the fact that they were responsible corporate officials at the time these offenses occurred. The statute which formed the basis for the guilty pleas requires no proof of intent or actual knowledge of the violations by the corporate officials to establish their guilt for the misdemeanor offense. The intent of the statute, as explained in the United States Supreme Court's decision in *United States v. Park*, 421 U.S. 658, 676 (1975), is to impose the highest standard of care on certain corporate officials having authority over business organizations involved in activities regulated by the Federal Food, Drug, and Cosmetic Act. Under the United States Sentencing Guidelines, the guideline range for these defendants was 0-6 months. While we believe corporate officials must be held accountable for the actions of the company, a sentence of incarceration based on a strict liability offense for defendants with no prior criminal history would be unusual.

The Impact of the Convictions on Future Corporate Misconduct

It is our judgment that even without a sentence of incarceration, conviction of the corporate officials will have significant consequences. Each corporate official will bear the stigma of being a convicted criminal, and the Court has imposed a term of probation of 3 years and ordered each defendant to perform 400 hours of community service and pay significant monetary fines. During the time period of probation, each defendant will live with the knowledge that any violation of probation can result in a sentence of imprisonment. Also, these unique guilty pleas by the company's three top executives are likely to have a significant positive impact on the pharmaceutical industry by emphasizing the high standard of care that the law recognizes for those with authority over the activities of business organizations. While the strict liability misdemeanor for misbranding has been in effect for a great number of years, it has rarely been used against company executives for misbranding a pharmaceutical product. I believe that the plea agreements and the resulting finding of guilt against the corporate officials will serve as a strong warning to executives of other pharmaceutical companies that they, too, will be expected to exercise the highest standard of care and diligence in the supervision and management of company activities and the actions of their subordinates to avoid the potential for appearance in a Federal courtroom to face criminal charges. In addition, the contemplated non-incarcerative sentences are part of an overall negotiated resolution of a criminal investigation that will accomplish the objective of holding accountable a company and its executives for criminal conduct that had previously not been addressed.

Victims of OxyContin and the Impact of the Convictions

Finally, I would like to address the human element to this case. I have spoken to many people who have been harmed or who have had a loved one harmed by OxyContin. People like Marianne Skolek, whose daughter Jill died from OxyContin on April 29, 2002, and whose little boy Brian will now have to grow up without his mom. Although there are complex legal questions about the relationship between Purdue's crimes and the events that have led to

such harm, the stories of those who have lost a loved one are heartbreaking. As a prosecutor I have seen the aftermath of terrible crimes and witnessed much sadness, but that doesn't make it any easier to hear about the death and separation caused by OxyContin. As a parent of two small children, I cannot imagine the pain that these people have suffered, and I pray that they can find some peace. I also recognize that the convictions of Purdue and its executives, although important, offer little comfort to people like Marianne and Brian.

My hope is these convictions can serve some purpose for these individuals, however. Many people, especially Ms. Skolek, have been raising concerns about Purdue and its conduct for years. And most of these people weren't saying that Purdue was solely responsible for their loved one's deaths - they just wanted Purdue to tell the truth about the drug. This case has exposed that truth. This prosecution also has given them a forum to publicly face the top three executives of Purdue and express their true feelings. It has confirmed what they believed for a very long time - that the marketing of OxyContin was deceptive and criminal. By convicting this company and its executives and imposing serious sanctions, perhaps these individuals can find some relief and a measure of closure. These individuals have stood up for truth and the Federal prosecution proved to these individuals and the world that Purdue and its executives committed Federal crimes for which they were held accountable. The Federal prosecution demonstrated that Purdue is a company that was guilty of false and misleading statements to maximize its profits.

Again, I thank the Committee for allowing me to speak today.